IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION **THIS DOCUMENT RELATES TO:** *Tina Burris v. Ethicon, Inc.* Civil Action No. 2:14-cv-24320	**Master File No. 2:12-MD-02327** **MDL No. 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

RULE 26 EXPERT REPORT OF DR. NIALL GALLOWAY

The following report is provided pursuant to Rule 26 of the Federal Rules of Civil Procedure. The opinions, which are held and expressed are as follows:

I. QUALIFICATIONS

I am an Associate Professor of Surgery (Urology) at the Emory University School of Medicine in Atlanta, Georgia. I obtained a M.B., Ch.B. from the University of Aberdeen Medical School in 1974 and went on to Edinburgh, Scotland for internship. I was awarded Fellowship of the Royal College of Surgeons of England in 1979 and was later awarded Fellowship of the Royal College of Surgeons of Edinburgh. I completed my residency in surgery in 1980 at Royal United Hospital in Bath, England.

I was appointed Lecturer in Surgery/Urology at the University of Edinburgh in 1982. At that time, I was able to initiate collaboration between the Urology and Gynecology specialties, which led to the creation of the first multidiscipline Continence Clinic in Scotland. I was appointed Senior Registrar in 1984 at the University Hospital of Wales in Cardiff. In 1986, I was invited to Duke University as a Research Fellow and was later appointed to the faculty as visiting professor. I was invited to join the faculty of Emory University School of Medicine in Atlanta in 1988. In 1992, I co-founded the Emory Continence Center, where I presently serve as Medical Director. The Continence Center is staffed by Urology, Gynecology and Gastroenterology physicians, as well as specialty trained continence nurses. The center provides all aspects of comprehensive assessment and treatments for pelvic floor dysfunction including incontinence, prolapse, bowel problems, and pelvic pain.

I was elected to the Atlanta Urological Association in 1990, the Southeastern Section of the American Urological Association AUA in 1993, and by invitation to the National Urological Forum in 1994. From 2007 to 2008, I served on the Medical Executive

Committee of the Georgia Urological Association. I have recently stepped down from the position of Chairman of the Board of Directors for the National Association for Continence, after serving two consecutive terms. I have been a member of the editorial board for the European Association of Urology since 2011. I am an author of many book chapters, abstracts, and peer reviewed journal articles and have given presentations regarding pelvic floor disorders, including pelvic organ prolapse (POP) and stress urinary incontinence (SUI). I have recently published a new book titled "Seeking Symmetry: Finding Patterns in Human Health".

My experience, education, and training are more fully summarized in my curriculum vitae, attached to this report as Exhibit A.

II. INTRODUCTION

Over the past several years, more and more of my surgical practice consists of handling complications resulting from the placement of synthetic mesh in the vagina for POP and SUI. I see several new patients every month with mesh-related complications. Synthetic mesh can take a trivial condition and raise a host of aggravating problems that interfere with activities of normal life. Surgeons and physicians saw these problems soon after these products were introduced. The most common complaints are pain and dyspareunia from banding, scarring, shrinkage, and contraction of the mesh.

In the introduction of trans-vaginally-placed mesh devices into the medical marketplace for the treatment of SUI, a basic principle of medicine was violated; that is, "Do No Harm." These products were introduced into the marketplace despite red flag alerts from the hernia experience and literature, the known uniqueness of the vaginal environment, and early adverse event reports. As a result, a public health crisis has been created. Women have been forced to deal with serious and unanticipated complications and doctors have been confronted with conditions that are difficult, and sometimes impossible, to treat. All of this was predictable.

The opinions expressed in this report are based on my experience treating women with mesh complications and surgically removing mesh and the medical and scientific literature. All my opinions have been made to a reasonable degree of medical certainty.

III. DISCUSSION

The extrapolation of the placement of mesh in other parts of the body (e.g., the abdominal wall) to the vagina was an erroneous idea. The vagina is a unique environment. Although the vagina can be forgiving (as in accommodating a vaginal birth and the remarkable healing afterwards), it can also be as hostile as any area in the human body. The vagina is also extremely variable from one individual to the next and over time. Synthetic mesh devices failed to take into consideration biological and anatomical differences of the vagina.

1. A permanent synthetic mesh device designed to be placed in a contaminated environment (i.e., vagina) contradicts basic surgical principles.

The vagina is populated and colonized with numerous bacteria and yeast and is located immediately adjacent to the bowel and anus.

The vagina is the only area of the body in which polypropylene mesh is placed in a bacteria laden surgical field. In fact, the placement of polypropylene mesh is actually contraindicated in this setting. Choi reported on the outcomes of 33,832 cases of ventral hernia repair with mesh. The authors of this study concluded, "there is a significant increase in risk of postoperative occurrences following VHRs [ventral hernia repairs] using mesh in clean-contaminated and contaminated cases relative to clean cases." The study recommended avoiding the use of mesh in any level of contamination.[1]

Culligan and others have shown that bacterial colonization exists even after attempts to sterilize the vagina in preparation for surgery. Even following standard surgical scrub with providone-iodine and pre-operative antibiotics, the majority of women (52%) had positive cultures at 30 minutes. Bacteria found in baseline (preoperative) vaginal cultures included anaerobic pathogens (45%), staphylococcus aureus (16%), alpha-hemolytic streptococcus (23%), E. coli (42%), klebsiella pneumonia (13%), and Group B streptococci (13%).[2]

Synthetic mesh materials are prone to infections and "notoriously resistant to antibiotics and host defenses, and to persist until the biomaterial is removed."[3] In a prospective study of 64 consecutive patients undergoing vaginal implantation of a lightweight, collagen-coated monofilament polypropylene mesh, Vollebregt, et al. showed that 96 % of the mesh arms were colonized by different types of bacteria.[4] The bacteriological analysis of 16 meshes removed because of complications following the surgical management of urinary incontinence or POP showed multimicrobial infection in 31% of cases, including P. mirabilis (in 25%), E. coli, Staphylococcus, Streptococcus and

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[1] Choi, J. J., Palaniappa, N. C., Dallas, K. B., Rudich, T. B., Colon, M. J., & Divino, C. M. (2012). Use of mesh during ventral hernia repair in clean-contaminated and contaminated cases: outcomes of 33,832 cases. Ann Surg, 255(1), 176-180. doi: 10.1097/SLA.0b013e31822518e6.

[2] Culligan, P., Heit, M., Blackwell, L., Murphy, M., Graham, C. A., & Snyder, J. (2003). Bacterial colony counts during vaginal surgery. Infect Dis Obstet Gynecol, 11(3), 161-165. doi: 1080/10647440300025515.

[3] de Tayrac, R., & Letouzey, V. (2011). Basic science and clinical aspects of mesh infection in pelvic floor reconstructive surgery. Int Urogynecol J, 22(7), 775-780. doi: 10.1007/s00192-011-1405-4.

[4] Vollebregt, A., Troelstra, A., & van der Vaart, C. H. (2009). Bacterial colonisation of collagen-coated polypropylene vaginal mesh: are additional intraoperative sterility procedures useful? Int Urogynecol J Pelvic Floor Dysfunct, 20(11), 1345-1351. doi: 10.1007/s00192-009-0951-5.

Enterococcus [8]. Bacterial contamination was found in all meshes, even in a case of repeat surgery for mesh shrinkage with no erosion. Bacterial density was low (<103 CFU/mL) in 43% of cases but in others reached 10^5 CFU/mL.[5]

Lactobacilii dominate the normal bacteria seen in the vagina and routinely produce hydrogen peroxide and lactic acid. "Their toxic and inhibitory effect against the overgrowth of pathogens in the vagina is documented by in vitro studies."[6] This issue becomes important since peroxides are implicated in the oxidation and degradation of polypropylene in the human body.

Infection, even subclinical, has been linked with misbehaving mesh and mesh complications, including chronic infection and abscess, wound separation, erosion, fistulae, shrinkage, chronic inflammation, degradation, and functional bladder problems. In a study by Wang, bacterial colonization was also linked to de novo urge symptoms after placement of mesh. In that study, 83% of patients with urge symptoms had bacteria identified in the excised tissue, compared to 5% in controls.[7]

The difference in the abdomen and vagina was demonstrated as early as 2000. Visco et al., reporting on their experience with sacral colpopexy, noted that "the rate of mesh erosion is higher and the time to mesh erosion is shorter with combined vaginal-abdominal sacral colpoperineopexy with vaginal suture and vaginal mesh placement in comparison with abdominal sacral colpopexy." The erosion rate with traditional sacral colpopexy was noted to be 4.5% whereas the erosion rate when mesh was placed vaginally was 40%. As a result, the investigators discontinued the practice of attaching vaginal mesh directly to the perineal body and concluded that "mesh erosions may be the only clinical manifestations of a bacterial contamination."[8]

It was foreseeable that placing mesh in a contaminated environment would create problems, e.g. de novo infection, abscess, erosion, and pain.

In my opinion, inserting polypropylene mesh (known to be problematic when placed in a contaminated field) in the vagina (known to contain bacteria, known to be

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[5] Boulanger, L., Boukerrou, M., Rubod, C., Collinet, P., Fruchard, A., Courcol, R. J., & Cosson, M. (2008). Bacteriological analysis of meshes removed for complications after surgical management of urinary incontinence or pelvic organ prolapse. Int Urogynecol J Pelvic Floor Dysfunct, 19(6), 827-831. doi: 10.1007/s00192-007-0537-z.

[6] Mijac, V. D., Dukic, S. V., Opavski, N. Z., Dukic, M. K., & Ranin, L. T. (2006). Hydrogen peroxide producing lactobacilli in women with vaginal infections. Eur J Obstet Gynecol Reprod Biol, 129(1), 69-76. doi: 10.1016/j.ejogrb.2005.11.036.

[7] Wang, A. C., Lee, L. Y., Lin, C. T., & Chen, J. R. (2004). A histologic and immunohistochemical analysis of defective vaginal healing after continence taping procedures: a prospective case-controlled pilot study. Am J Obstet Gynecol, 191(6), 1868-1874. doi: 10.1016/j.ajog.2004.09.017.

[8] Visco, A. G., Weidner, A. C., Barber, M. D., Myers, E. R., Cundiff, G. W., Bump, R. C., & Addison, W. A. (2001). Vaginal mesh erosion after abdominal sacral colpopexy. Am J Obstet Gynecol, 184(3), 297-302. doi: 10.1067/mob.2001.109654.

close to the anus, and known to be incapable of sterilization) represents a serious flaw in the design of Ethicon's mesh devices.

2. Polypropylene becomes rigid when placed in the vagina - an organ that needs to remain flexible and compliant to function. This phenomenon leads to complications not seen with traditional pelvic surgery.

The pelvic floor is a dynamic trampoline of resilient muscles and connective tissue structures. It needs to be supple, flexible, and springy. The muscles and loose connective tissue are critical for normal pelvic support. They must contract to maintain pelvic support for continence. They must relax to permit voluntary urination and to initiate the act of defecation. In the female, the pelvic floor must relax and lengthen enormously to allow the passage of a full-term fetus during childbirth, yet it must contract again after delivery to permit all of the normal functions to be maintained. It must accommodate movement and forces associated with activities of daily living, such as coughing, walking, exercise, bladder filling, defecation, and sexual relations. Scar plate and mesh stiffness are incompatible with the natural functioning of the vagina.

Mesh embrittlement, resulting in restriction of movement of the abdominal wall, has been recognized in hernia repairs for some time. In 2001, Junge and Klinge used fresh cadavers to test the elasticity of abdominal wall mesh. The authors reported that the implantation of mesh "leads to considerable restriction of abdominal wall mobility in up to 25% of cases. Rigidity and discomfort, especially at the edge of the mesh, are frequent reported complaints." Junge stated that tensile strength and flexibility must be taken into account in the "complex interactions of the anatomic structures" where the mesh is placed. Inadequate pore size and geometry result in increased shrinkage and scar reaction. Junge found most of the meshes he tested to be "inappropriately stiff" and these turned into a "hard sheet in the post-implantation period."[9]

"The mechanism of action of a permanent prosthetic mesh is to incite an intense fibroplastic foreign body response, resulting in the development of a strong scar plate interface. Although this may provide a strong and durable repair, the chronic inflammatory response to the mesh may also lead to chronic pain in some patients, a sensation of being able to feel the mesh, and stiffness of the abdominal wall with loss of compliance."[10] In addition to stiffness from scarring and fibrosis, degradation of the polymer itself results in stiffening.[11]

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[9] Junge, K., Rosch, R., Klinge, U., Schwab, R., Peiper, C., Binnebosel, M., . . . Schumpelick, V. (2006). Risk factors related to recurrence in inguinal hernia repair: a retrospective analysis. Hernia, 10(4), 309-315. doi: 10.1007/s10029-006-0096-0.

[10] Bellows, C. F., Shadduck, P. P., Helton, W. S., & Fitzgibbons, R. J. (2011). The design of an industry-sponsored randomized controlled trial to compare synthetic mesh versus biologic mesh for inguinal hernia repair. Hernia, 15:325-332. doi: 10.1007/s10029-010-0773-x.

[11] Costello CR, Bachman SL, Ramshaw BJ, Grant SA. Materials characterization of explanted polypropylene hernia meshes. Journal of biomedical materials research Part B, Applied biomaterials. 2007;83(1):44-9; C.R.

The loss of vaginal compliance and function from hardened mesh is something I commonly see in my practice. Mesh, when surgically removed, does not look or feel anything like it does in the package.

In my opinion, placing polypropylene mesh (known to become rigid and restrictive of motion) in the vagina (known to require flexibility and compliance for proper function) represents a serious flaw in the design of Ethicon's vaginal mesh devices.

3. Degradation, chronic inflammation, and possible toxicity create unknown long-term effects in a woman's vagina.

A chronic inflammatory and foreign body reaction to transvaginally placed mesh occurs in all patients.[12] Additionally, Polypropylene was known to degrade in the human body as early as 1986[13]. This was reported again by Coda and Bendavid in 2003[14] and frequently since that time. Degradation and mesh surface changes contribute to the inflammatory response and scar plate formation by harboring bacteria, releasing toxins, and creating a jagged surface. In a 2007 study of explanted polypropylene hernia mesh, Costello et al. reported cracks, surface roughness, and peeling – all indicative of degradation. The authors also recognized reduced compliance. "These findings correspond to increased abdominal wall stiffness and patient complaints of pain and restricted mobility. During the implantation period, the surface of the explanted materials stimulated the foreign body response that, in turn, produced oxidants such as hydrogen peroxide and hypochlorous acid."[15]

Costello SLB, S.A. Grant, D.S. Cleveland, T.S. Loy and B.J. Ramshaw. Characterization of Heavyweight and Lightweight Polypropylene Prosthetic Mesh Explants From a Single Patient. Surgical Innovation. 2007;14(3):168-76.; Fayolle B, Audouin L, Verdu J. Oxidation induced embrittlement in polypropylene - a tensile testing study. Polymer Degradation and Stability. 2000;70(2000):333-40; Fayolle B, Audouin L, Verdu J. Initial steps and embrittlement in the thermal oxidation of stabilised polypropylene films. Polymer Degradation and Stability. 2002;75:123-9; Fayolle B, Audouin L, George GA, Verdu J. Macroscopic heterogeneity in stabilized polypropylene thermal oxidation. Polymer Degradation and Stability. 2002;77:515-22; Liebert TC, Chartoff RP, Cosgrove SL, McCuskey RS. Subcutaneous implants of polypropylene filaments. Journal of biomedical materials research. 1976;10(6):939-51; Anderson JM, Rodriguez A, Chang DT. Foreign body reaction to biomaterials. Seminars in immunology. 2008;20(2):86-100.

[12] Iakovlev V., C. E., Steege J (2014). "Pathology of Explanted Transvaginal Meshes." International Journal of Medical, Health, Pharmaceutical and Biomedical Engineering 8(9).

[13] Jongebloed, W. L., & Worst, J. F. Degradation of polypropylene in the human eye: a SEM-study. Documenta Ophthalmologica. Advances In Ophthalmology,1986: 64(1), 143-152.

[14] Coda, A., Bendavid, R., Botto-Micca, F., Bossotti, M., & Bona, A (2003). Structural alterations of prosthetic meshes in humans. Hernia: The Journal Of Hernias And Abdominal Wall Surgery, 7(1), 29-34

[15] Costello, C. R., Bachman, S. L., Grant, S. A., Cleveland, D. S., Loy, T. S., & Ramshaw, B. J. (2007). Characterization of heavyweight and lightweight polypropylene prosthetic mesh explants from a single patient. Surg Innov, 14(3), 168-176. doi: 10.1177/1553350607306356.

Clave confirmed degradation in transvaginal mesh explants in 2010. Clave questioned "the prevailing understanding of PP as inert" based on his examination of 100 explants. In Clave's work, "not all types of PP implants degraded equally. The PP implants degraded more in the presence of an acute infection or chronic inflammation." Clave considered several hypotheses for this degradation, including large detachments and hematomas causing the massive accumulation of blood-derived fatty acids, the diffusion of organic molecules into the polymer, and radical oxidation due to the septic environment that accompanies acute infections and chronic inflammation.[16] Several recent studies have confirmed degradation in explanted vaginal mesh.[17]

In my opinion, placing a material that degrades, releases potentially toxic chemicals, and creates a chronic inflammatory response, is a flaw in the design of Ethicon's vaginal mesh devices.

4. Ethicon's transvaginal mesh devices demonstrate a variable and unpredictable rate of shrinkage and retraction, rendering performance that is unreliable at best.

In 1998, Klinge and Klosterhalfen reported a 30-50% shrinkage rate with polypropylene mesh.[18] In practice, surgeons knew for even longer that a mesh piece must be cut significantly larger than the defect to avoid failure at the edges, indicating concern for shrinkage and puckering. Tunn confirmed shrinkage using ultrasound evaluation of transvaginal mesh in 2007.[19] Jacquetin and Cosson linked mesh retraction with vaginal tenderness, painful intercourse, pain, sometimes permanent, and possibly urinary dysfunction.[20]

Because of shrinkage and retraction, there is no way to place synthetic mesh in a "tension-free" manner and it is impossible to know how much tension will eventually

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[16] Clave, A., Yahi, H., Hammou, J. C., Montanari, S., Gounon, P., & Clave, H. (2010). Polypropylene as a reinforcement in pelvic surgery is not inert: comparative analysis of 100 explants. Int Urogynecol J, 21(3), 261-270. doi: 10.1007/s00192-009-1021-8.

[17] Iakovlev V. MG, Blaivas J. Pathological Findings of Transvaginal Polypropylene Slings Explanted for Late Complications: Mesh is Not Inert [Abstract]. International Continence Society Meeting Annual Meeting. 2014; Iakovlev V., C. E., Steege J (2014). "Pathology of Explanted Transvaginal Meshes." International Journal of Medical, Health, Pharmaceutical and Biomedical Engineering 8(9); Iakovlev, V., Guelcher, S., Bendavid, R. (2014). "In vivo degradation of surgical polypropylene meshes: A finding overlooked for decades." Virchows Arch Suppl 1: S35; Tzartzeva K, L. D., Baniasadi M, Minary-Jolandan M, Zimmern P (2014). "In-Depth Nan-Investigation of Vaginal Mesh and Tape Fiber Explants in Women [Abstract]." ICS 366.

[18] Klinge, U., Klosterhalfen, B., Muller, M., Ottinger, A. P., & Schumpelick, V. (1998). Shrinking of polypropylene mesh in vivo: an experimental study in dogs. Eur J Surg, 164(12), 965-969. doi: 10.1080/110241598750005156.

[19] Tunn, R., Picot, A., Marschke, J., & Gauruder-Burmester, A. (2007). Sonomorphological evaluation of polypropylene mesh implants after vaginal mesh repair in women with cystocele or rectocele. Ultrasound Obstet Gynecol, 29(4), 449-452. doi:10.1002/uog.3962.

[20] Jacquetin, B., & Cosson, M. (2009). Complications of vaginal mesh: our experience. Int Urogynecol J Pelvic Floor Dysfunct, 20(8), 893-896. doi: 10.1007/s00192-009-0926-6.

result. The degree of shrinkage is unpredictable and varies from one individual to the next – some women are high responders and others are low responders to biomaterials, including polypropylene. The amount of shrinkage has also been shown to vary based on the location in which it is placed (between the peritoneum and muscle or above the fascia).[21] Shrinkage is magnified with infection, even subclinical contamination, which has been found to occur in almost all transvaginally placed meshes.[22] Letouzey showed polypropylene mesh contraction to be progressive, demonstrating a linear evolution with time. Ultrasound reconstruction "showed a mean contraction of 30%, 65%, 85% at a mean follow up of 3 years (n 5 12), 6 years (n 5 16), 8 years (n 5 12) respectively."[23]

Chronic pelvic pain is the most common clinical symptom associated with mesh shrinkage. "The concurrent processes of tissue in growth and mesh shrinkage may cause significant pain, particularly in patients who undergo trocar-guided mesh placement. Adherence of the mesh arms in the lateral pelvic wall is a point against which tension increases during the processes of tissue in growth and mesh shrinkage." Other complications related to shrinkage and not warned about by Bard include sexual impairment, loss of vaginal function due to narrowing/shortening, functional bladder and bowel symptoms, and need for multiple, difficult corrective procedures.[24] Chronic pain from mesh distortion and shrinkage is something I commonly see in my practice.

In a study by Margulies, "[t]he repercussions of mesh shrinkage in the vagina vs the abdominal wall can be severe and functionally devastating. Normal urinary, sexual, and defecatory functions require a vagina that is compliant and whose walls can easily and painlessly change conformation. With excessive stiffness of the vaginal walls secondary to mesh that has undergone shrinkage, it is possible that dyspareunia, defecatory, and urinary dysfunction could result." The conditions described in this article are something I commonly see in my practice.[25]

An example of a clinical study exhibiting the defects in armed transvaginal mesh was published by Feiner and Maher in 2010, based on a series of patients seen in 2007-2008. This paper described the "substantial morbidity" associated with "vaginal mesh contraction". "Clinical presentation included severe vaginal pain aggravated by

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[21] Garcia-Urena, M. A., Vega Ruiz, V., Diaz Godoy, A., Baez Perea, J. M., Marin Gomez, L. M., Carnero Hernandez, F. J., & Velasco Garcia, M. A. (2007). Differences in polypropylene shrinkage depending on mesh position in an experimental study. Am J Surg, 193(4), 538-542. doi: 10.1016/j.amjsurg.2006.06.045

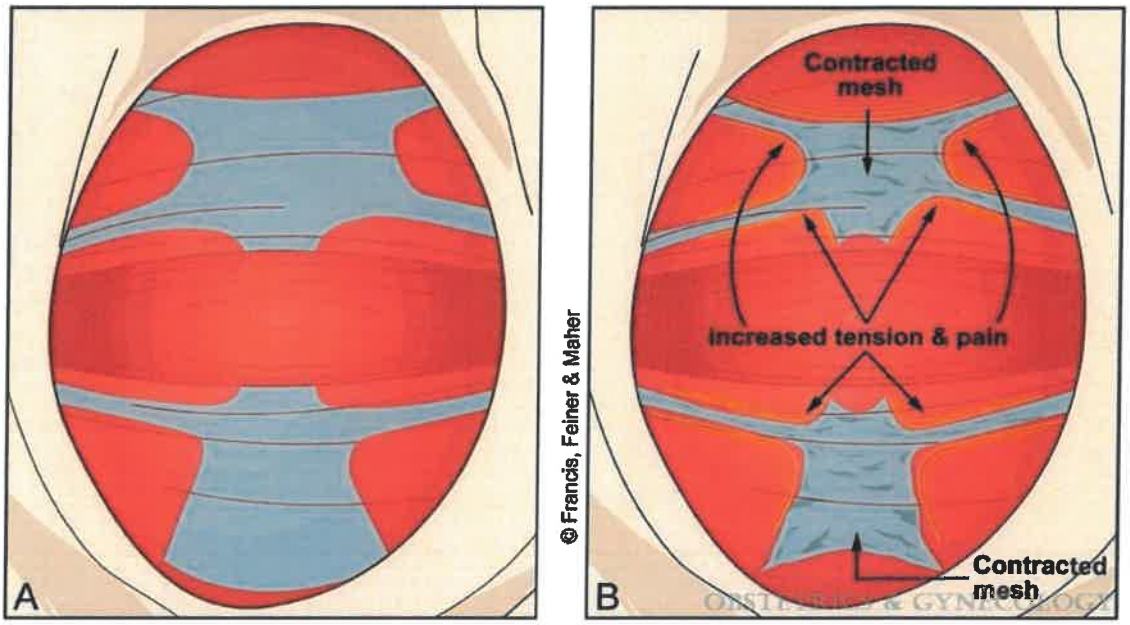
[22] Mamy, L., Letouzey, V., Lavigne, J. P., Garric, X., Gondry, J., Mares, P., & de Tayrac, R. (2011). Correlation between shrinkage and infection of implanted synthetic meshes using an animal model of mesh infection. Int Urogynecol J, 22(1), 47-52. doi: 10.1007/s00192-010-1245-7.

[23] Letouzey, V., Huberlant, S., Lavigne, J., Mares, P., Garric, X. & De Tayrac, R. (2012). Is polypropylene mesh coated with antibiotics is efficient to prevent mesh infection and contraction in an animal infectious model? [Abstract]. 37th Annual Meeting of the International Urogynecological Association, 193.

[24] Rogo-Gupta, L., & Raz, S. (2013). Pain Complications of Mesh Surgery. In H. B. Goldman (Ed.), Complications of Female Incontinence and Pelvic Reconstructive Surgery (pp. 87-105): Humana Press.

[25] Margulies, R. U., Lewicky-Gaupp, C., Fenner, D. E., McGuire, E. J., Clemens, J. Q., & Delancey, J. O. (2008). Complications requiring reoperation following vaginal mesh kit procedures for prolapse. Am J Obstet Gynecol, 199(6), 678 e671-674. doi: 10.1016/j.ajog.2008.07.049.

movement (17 of 17), dyspareunia in all sexually active women (14 of 14), and focal tenderness over contracted portions of the mesh on vaginal examination (17 of 17), commonly involving the lateral fixation arms. Mesh erosion (9 of 17), vaginal tightness (7 of 17), and shortening (5 of 17) were frequently present." This paper set out to describe the clinical implications of the in vivo shrinkage of polypropylene mesh up to 50% if its original size that had been previously described both in animal studies and women.[26] Vaginal contraction from mesh procedures is something I commonly see in my practice.



Feiner, Benjamin; Maher, Christopher: Obstetrics & Gynecology. 115(2, Part 1): 325-330, February 2010.

In my opinion, using a material that shrinks and retracts significantly, but in a variable and asymmetric fashion, is a flaw in design.

5. Ethicon's transvaginal mesh devices damage and entrap nerves, sometimes resulting in chronic and permanent pain syndromes that are refractory to treatment.

Unlike routine postoperative pain that is typically self-limiting, mesh-related pain is often atypical in character, onset, duration, and location. Neuropathic pain associated with mesh is something I see commonly in my practice and can be very difficult to treat.

Nerve injuries occur commonly with transvaginally placed mesh. The trocars,

[26] Feiner, B., & Maher, C. (2010). Vaginal mesh contraction: definition, clinical presentation, and management. Obstet Gynecol, 115(2 Pt 1), 325-330. doi: 10.1097/AOG.0b013e3181cbca4d.

blindly placed, traverse through tissue densely innervated with large nerves and smaller nerve branches. Nerves can be traumatized during the procedure itself. Postoperative nerve injuries have been reported to occur at a rate of 9.4% with transobturator slings.[27]

Nerve damage can also result from nerve inflammation and nerve entrapment resulting from the chronic inflammatory response and fibrosis surrounding the mesh. The nerves most commonly involved with a transobturator sling are the intermediate femoral cutaneous, posterior cutaneous, pudendal, perineal, inferior anal, and the obturator nerves. The ilioinguinal and iliohypogastric nerves are more commonly involved with the retropubic approach.

In a 2005 Klosterhalfen post-retrieval study of hernia mesh, most explants from all the patients with chronic pain in their medical history indicate nerve fibers and fascicles in the interface of the mesh. Klosterhalfen further stated that "clinical trials report high percentages of patients with chronic pain after hernia repair, including mesh repair. In contrast to neuropathy-related complaints after intraoperative damage of nerve fibers with pain immediately after surgery, the onset of chronic pain as a consequence of the FBR [foreign body reaction] is typically more than 1 year after hernia repair. In the postretrieval study, most explants from all the patients with chronic pain in their medical history, indicate nerve fibers and fascicles in the interface of the mesh."[28]

Drs. Iakovlev and Ben-David recently published an article in the peer-reviewed literature titled, "Mesh-Related SIN Syndrome. A Surreptitious Irreversible Neuralgia and Its Morphologic Background in the Etiology of Post-Herniorrhaphy Pain". This paper describes nerve ingrowth with hernia mesh and reports a new mesh-related pain disorder characterized by its slow onset, its progressive and unrelenting nature, and its unresponsiveness to treatment including mesh removal.[29] Drs. Iakovlev and Blaivas have also published their findings of nerve damage in vaginal mesh – occurring with a much greater density than the abdominal wall. These published reports of explanted mesh pathology also describe chronic inflammation, scarring and fibrosis, deformation, and degradation.[30]

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[27] Richter, H. E., Albo, M. E., Zyczynski, H. M., Kenton, K., Norton, P. A., Sirls, L.T., Litman, H. J. (2010). Retropubic versus transobturator midurethral slings for stress incontinence. N Engl J Med, 362(22), 2066-2076. doi: 10.1056/NEJMoa0912658.

[28] Klosterhalfen, B., Junge, K., & Klinge, U. (2005). The lightweight and large porous mesh concept for hernia repair. Expert Rev Med Devices, 2(1), 103-117. doi:10.1586/17434440.2.1.10.

[29] Bendavid, R., Lou, W., Koch, A., Iakovlev, V. (2014). "Mesh-Related SIN Syndrome. A Surreptitious Irreversible Neuralgia and Its Morphologic Background in the Etiology of Post-Herniorrhaphy Pain." International Journal of Clinical Medicine 5: 799-810.

[30] Iakovlev V., M. G., Blaivas J. (2014). "Pathological Findings of Transvaginal Polypropylene Slings Explanted for Late Complications: Mesh is Not Inert [Abstract]." International Continence Society Meeting Annual Meeting.

Histological findings in transvaginal mesh:

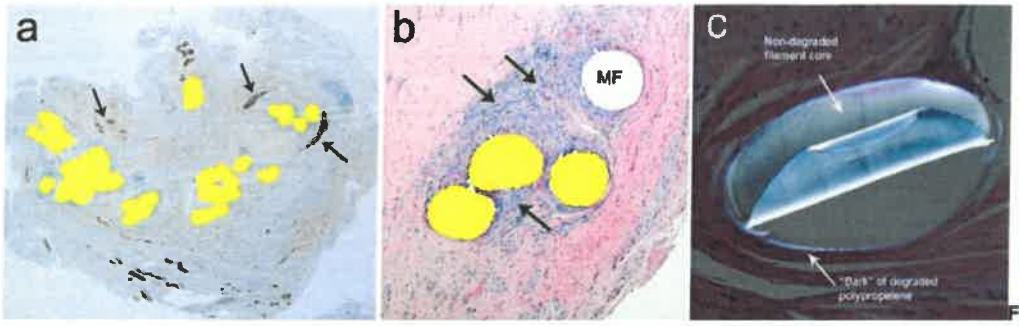

Figure 1. a: Nerve ingrowth. 2.5x objective, S100 stain to highlight nerves (dark brown, some nerves pointed by arrows). Mesh filaments are filled yellow for demonstration. b: Foreign body and non-specific chronic inflammation. H&E stain, 20x objective, three filaments filled yellow, one left unfilled (MF), inflammation pointed by arrows. c: Polypropylene degradation. 40x objective, partially polarized light. The bark of degraded polypropylene surrounds the central core (in the picture the core detached and folded). Both, the core and the bark show the same polarizing properties (brightly lit). The bark absorbs histological dyes due to it porosity and stains purple while the core remains clear (MF filament left clear in panel "b").

Rogo-Gupta stressed the importance of a thorough understanding of pelvic anatomy in evaluating complex mesh pain.[31] Mesh can become incorporated into muscles, resulting in fibrosis, restriction and pain with movement. Muscular injury with armed mesh may cause severe pain with walking or joint movement. Patients who undergo posterior compartment mesh repair with trocar-guided lateral mesh arms may experience pain in the levator muscles or gluteus maximus. Gluteus maximus innervation is provided by the inferior gluteal nerve (S1). Patients may present with pain exacerbated by sitting, external hip rotation, and hip extension. Injury to the external anal sphincter muscles may cause pain or defecatory dysfunction including constipation or incontinence of flatus or stool. Intraoperative nerve damage presents immediately following the procedure. Sharp pain in a specific nerve distribution presenting in the immediate postoperative period suggests intraoperative nerve damage and should be treated.

"Nerve pain that presents in the postoperative period and persists into the delayed postoperative period should be considered an example of mesh pain and trigger evaluation for other etiologies as well. This includes nerve entrapment and the pelvic organ cross-talk or sensitization. Posterior compartment repair may cause injury to the lumbosacral plexus, sciatic nerve, or pudendal nerve."[32]

Chronic mesh pain syndrome (CMPS) is reported in the medical literature and refers to a complex condition that develops in some patients with pain following mesh reconstruction. This pain persists beyond the routine postoperative period and is characterized by its intensity. It is also refractory to medical and surgical treatment. Regional and systemic symptoms develop as a result of nerve up-regulation, cross-talk and central sensitization. CMPS is a pathologic condition caused by the transformation of

[31] Rogo-Gupta (2013).
[32] Rogo-Gupta (2013).

local vaginal pain into a multiorgan systemic process.[33]

The potential for serious pain conditions resulting from the transvaginal mesh should have been apparent from the experience of hernia mesh in the abdominal wall and elsewhere in the body. Chronic pain is the most serious long-term complication that can occur after repair of groin hernia. The incidence of chronic pain after herniorrhaphy has been reported to be 30% or even higher. The complaint of chronic pain after inguinal hernia repair continues for months or even years. The development of chronic pain has been attributed to several mechanisms, including damage to sensory nerves and mesh inguinodynia.

In my opinion a medical device that injures and entraps nerves and muscle, sometimes resulting in chronic, severe, and intractable pain conditions, is flawed.

6. Because of the unique design of the pelvic organ system, Ethicon's transvaginal mesh devices can result in bowel problems, bladder problems, and sexual dysfunction.

The vagina is a dynamic organ that must respond to motion and dynamic changes in adjacent organs (bowel and bladder) and with sexual relations. The space is shared and confined between all the pelvic organs and they need to move in relation to one another.

If nerves and muscles are present and are functioning properly, the pelvic floor is a versatile dynamic structure with the possibility of fine regulation of muscle activity. The innervation of the lower urinary tract is complex and includes sensory and motor functions as well as somatic and autonomic systems. The urethra is like the mouth or the larynx, innervated by the right and left. Motor neurons and muscle fibers are arranged in independent functional units called motor units, and a limited number of motor units are responsible for muscle control. The greater the number of motor nerurons to the urinary sphincter, the greater the number of motor units, and the more versatile the range of possible muscle activity. Conversely, the lesser the number of motor neurons, the less versatile or more clumsy the possible range of sphincter activity. Patients with neurologic deficits in the pelvis may demonstrate irritative bladder symptoms and variable degrees of voiding difficulty and dysfunction.

Anorectal and bowel problems, likewise, are mediated by a complex arrangement of nerves and muscles in the pelvis. The normal act of defecation is easy and complete. The bowel should function with the effortless displacement of the stool from the lower bowel. After normal defecation, the sigmoid colon and rectum are empty and the stool is gone. If there is impairment of the nerves and muscles of the lower bowel, the function is more likely to be incomplete, and instead of the train leaving the station, only one or two cars might leave, but the bulk of the train continues to stand. The rectum and sigmoid

[33] Rogo-Gupta (2013).

colon remain loaded with stool most of the time. Constipation, diarrhea, irritable bowel symptoms, and pain can be associated with the loss of versatile sphincter and pelvic floor function.

Shared nerves means shared behaviors, and Kaplan et al. described this phenomenon as "crosstalk", the functional relationship between bladder and bowel. "The connection between bladder and bowel function is apparent in several clinical disorders, including chronic pelvic pain syndromes, urinary and faecal incontinence, organic diseases involving the colon, functional bowel disorders and OAB."[34]

In my opinion, a device designed for treatment of SUI or POP that invites widespread bladder, bowel and sexual dysfunction is flawed.

7. A permanent device that cannot be removed when complications dictate is unacceptable.

The medical literature contains numerous reports describing the difficulties and less than satisfactory outcomes associated with mesh removal. Those of us who are performing these surgeries on a regular basis know all too well the challenges of explant surgery. Putting mesh in is relatively easy. Taking it out is another matter. These surgeries are time-consuming, complicated, and risky for the patient. We never know what we will encounter until we get to the operating room. The anatomy is often distorted and healthy tissue often has to be removed along with the mesh. In many instances, it is impossible to remove the entire device. We are always concerned about the possibility of doing more harm than good. This is an entirely different situation from the treatment of any other surgical complication.

Rogo-Gupta described the technically challenging removal of armed mesh. "To successfully remove armed mesh segments in their entirety, the obturator membrane must be perforated and dissection carried out laterally. Additional incisions in the thighs may be required to adequately free the arms from the surrounding soft tissues. We suggest preoperatively marking the lateral puncture sites to facilitate intraoperative dissection. If the lateral incisions cannot be identified by patient symptoms or scarring, gentle traction on the medial portion of the mesh arms may be used as a guide. The mesh should be followed from skin incision to the intersection of the adductor muscles and dissected free in a circumferential fashion. Muscle fibers often must be dissected when mesh has become incorporated into the surrounding fibers. Large defects in the vaginal wall may occur with mesh removal and surgeons ought to be prepared to utilize rotational vaginal flaps, labial flaps, or skip flaps for reconstruction. Following complete healing and resolution of other symptoms such as pain, infection, bleeding, urinary or defecatory

[34] Kaplan, S. A., Dmochowski, R., Cash, B. D., Kopp, Z. S., Berriman, S. J., & Khullar, V. (2013). Systematic review of the relationship between bladder and bowel function: implications for patient management. Int J Clin Pract, 67(3), 205-216. doi: 10.1111/ijcp.12028

dysfunction, evaluation for additional surgery for persistent incontinence or prolapse can begin if clinically indicated."[35]

Reynolds et al. reported a series of patients in which obturator dissection was performed via a lateral groin incision over the inferior pubic ramus at the level of the obturator foramen, typically in conjunction with orthopedic surgery. All the patients in the series presented with "recalcitrant and devastating" groin pain after a transobturator sling procedure (5% to 16% of patients). According to the authors, "Groin pain after transobturator procedures is believed to be related to obturator nerve damage or entrapment and to resulting neuropathy. In addition, it may be nonneural in origin, and related to tension between the mesh material and adductor tissues." In transobturator procedures, the "trocar and mesh penetrate several muscles and structures of the inner thigh and pelvis, including (in order from external to internal) the gracilis muscle, adductor brevis muscle, obturator externus muscle, obturator membrane, obturator internus muscle and periurethral endopelvic connective tissue." Intraoperatively, the mesh was typically "closely associated to or traversing the adductor longus muscle and tendon insertion with significant fibrous reaction in all cases, and in 1 case the mesh was intimately associated with the obturator neurovascular bundle." The authors noted the dispute over the best timing for removal of a sling when pain develops postoperatively, an issue should have been resolved before marketing a device.[36]

Barber reported that the rate of requiring additional surgery for mesh complications is almost 50% in some series and seems to be higher in those undergoing partial excision at the initial operation. Recurrent pelvic organ prolapse was noted in 29% after complete excision and 5% of partial excisions. Dr. Barber described the removal of mesh for vaginal contraction, pain and dyspareunia, "If tenderness is focal and associated with a clearly defined contraction band, typically a lateral mesh arm, then transection of the contraction band without excision of the remaining mesh may provide adequate pain relief. If the tenderness is not localized or if release of the contraction band is not successful, then complete excision of the intravaginal portion of the mesh should be performed. This is done using the same technique as described previously for vaginal mesh exposure. The mesh arms should be transected as lateral as possible and all contraction bands released."[37]

Blandon also detailed the challenges of removal surgery. "The vaginal surgeon is faced with the challenges of very complex surgical dissections. If mesh excision is warranted, tissue fibrosis, scarring, bleeding, and urinary tract and anorectal injury are easily encountered, which add to patient morbidity...Moreover, whereas minor

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[35] Rogo-Gupta, 2013.

[36] Reynolds, W. S., Kit, L. C., Kaufman, M. R., Karram, M., Bales, G. T., & Dmochowski, R. R. (2012). Obturator foramen dissection for excision of symptomatic transobturator mesh. J Urol, 187(5), 1680-1684. doi: 10.1016/j.juro.2011.12.065.

[37] Barber, M. D. (2013). Surgical techniques for removing problematic mesh. Clin Obstet Gynecol, 56(2), 289-302. doi: 10.1097/GRF.0b013e3182856371.

complications such as small vaginal mesh erosions are simple and easy to manage, incapacitating pelvic pain, dyspareunia, and large-scale erosions can be exceedingly complex and not easily resolved."[38]

Crosby et al. at the University of Michigan, Ann Arbor, recently reported a 10-fold rise in the number of vaginal mesh removals in the past five years. The authors found that removal of vaginal mesh was helpful in relieving presenting symptoms, but complete resolution of symptoms, especially pain or dyspareunia, occurs in less than half of patients following excision.[39,40] Hartshorn also reported on mesh complications as an increasingly common indication for referral to tertiary care centers.[41] Pain resulting in deterioration of sexual function is a common symptom that is often managed by surgical removal of mesh. Based on this sample, surgical removal of mesh does not appear to improve pain related to sexual activity or overall sexual function. This has significance in the preoperative counseling of patients who are candidates for removal of transvaginal mesh.

My experience confirms the difficulty and often impossibility of removing the entire mesh product. Because of the location of mesh devices, tissue ingrowth, inflammation, and scar plate, removal surgery is often risky and complex. In most instances, remnants of mesh or mesh fibers are left behind. Multiple procedures may be required and results are often less than optimal, particularly when the mesh devices are removed for pain.

8. A literature review of transvaginally placed surgical meshes raises serious concerns about the safety and efficacy of these products for prolapse repair.

A product may be defective if the risks do not outweigh the benefits or is "not reasonably safe." Mesh kits for pelvic organ prolapse and SUI offer no benefits over traditional repairs.

The initial studies on efficacy of POP mesh kits seemed to demonstrate an anatomic improvement in the anterior compartment. These studies can now all be discredited for various reasons. There were never any benefits identified in the apical or posterior compartment, any reduction in reoperations for recurrent prolapse, or any improvement in Quality of Life measurements. In the past couple of years, several papers

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[38] Blandon, R. E., Gebhart, J. B., Trabuco, E. C., & Klingele, C. J. (2009). Complications from vaginally placed mesh in pelvic reconstructive surgery. Int Urogynecol J Pelvic Floor Dysfunct, 20(5), 523-531. doi: 10.1007/s00192-009-0818-9.

[39] Crosby, E. C., Berger, M. B. DeLancey, I.L., Fenner, D.E. & Morgan, D. M. (2012). Symptom resolution after operative management of complications from vaginal mesh. Female Pelvic Medicine & Reconstructive Surgery, 18 (5), 2.

[40] Crosby, E.C., Abernethy, M., Berger, M.B., DeLancey, J.O., Fenner, D.E., Morgan, D.M. (2014). Symptom Resolution After Operative Management of Complications From Transvaginal Mesh. Obstet Gynecol, 123(1), 134-139.

[41] Hartshorn, T.G., Rogo-Gupta, L., Tarvay, C.M., Rodriguez, L.V. & Raz, S. (2012). Sexual function after surgical removal of transvaginal mesh. AUGS, Poster Presentation 35.

have re-looked at the efficacy of native tissue repairs as compared to TVM procedures and found no improvements in efficacy.

The double-blinded randomized controlled trial initiated by Iglesia was halted because of excessive erosion, recently reported 3-year data on efficacy. Sokol and the other authors found cure rates and satisfaction after prolapse repair with and without mesh were high based on absence of prolapse beyond the hymen, lack of bulging symptoms and global impression of improvement (PGI-I).[42] This study draws into question the long-term value of vaginal mesh compared to native tissue repairs. Subjects in the mesh group suffered complications unique to vaginal mesh without long-term benefit as there was no perceived difference in success.

Stanford reviewed the literature on the success of traditional/native tissue success versus mesh-augmented repairs and found the "overall success rates of NT and MA repairs when recurrent prolapse is the primary outcome measure are very similar."[43] Oversand also found POP surgery using native tissue repair entails low reoperation rates with excellent subjective and objective results, few complications and should be the first choice in treating primary POP.[44] Funk and Visco analyzed 27,809 prolapse surgeries from an insurance database. The authors "found evidence that the use of mesh for anterior vaginal wall prolapse was associated with an increased risk of any repeat surgery, which was driven by surgery for mesh removal. Vaginal mesh and native tissue repair for anterior prolapse had similar 5-year risks for recurrent prolapse."[45]

I have reviewed the reliable scientific literature regarding the use of transvaginal mesh for prolapse repair. From these studies (and confirmed by my clinical experience), I have made the following conclusions regarding the efficacy of these products:

1. There is no good evidence supporting benefit in quality of life (QOL) or relief of symptoms in any compartment with the use of trans-vaginal mesh for the treatment of POP.
2. A recent study of 27,809 anterior prolapse surgeries with 49,658 person-years of follow-up determined that native tissue and vaginal mesh surgery had similar 5-year risks for surgery for recurrent prolapse.[46]

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[42] Iglesia, C. B., Sokol, A. I., Sokol, E. R., Kudish, B. I., Gutman, R. E., Peterson, J. L., & Shott, S. (2010). Vaginal mesh for prolapse: a randomized controlled trial. Obstet Gynecol, 116(2 Pt 1), 293-303. doi: 10.1097/AOG.0b013e3181e7d7f8.

[43] Stanford, E. J., Cassidenti, A., & Moen, M. D. (2012). Traditional native tissue versus mesh-augmented pelvic organ prolapse repairs: providing an accurate interpretation of current literature. Int Urogynecol J, 23(1), 19-28. doi: 10.1007/s00192-011-1584.

[44] Oversand, S. H., Staff, A. C., Spydslaug, A. E., Svenningsen, R., & Borstad, E. (2013). Long-term follow-up after native tissue repair for pelvic organ prolapse. Int Urogynecol J. doi: 10.1007/s00192-013- 2166-z

[45] Funk, M. J., Edenfield, A. L., Pate, V. & Visco, A. G. Trends in mesh use between vaginal prolapse repair and sacrocolpopexy, 2005-2010. Female Pelvic Medicine & Reconstructive Surgery, 18 (5), 2.

[46] Funk, M. J., Levin, P. J., & Wu, J. M. (2012). Trends in the surgical management of stress urinary incontinence. Obstet Gynecol, 119(4), 845-851.

3. There is no reduction in reoperation rates for prolapse in any compartment with the use of trans-vaginal mesh for the treatment of pelvic organ prolapse.
4. There is no evidence of anatomic benefit with the use of trans-vaginal mesh for the treatment of POP in the posterior or apical compartments.
5. There are studies that suggest anatomic benefit in the anterior compartment only, but this finding has limited, if any, clinical significance. Other studies show no anatomic benefit.
6. Recent studies indicate that the anatomic benefits (anterior compartment only) suggested in earlier trials are unfounded and the result of bias.
7. The total number of reoperations is higher in mesh repairs due to the rate of surgeries for repair of complications.

I have made the following conclusions regarding the safety of these products from my review of the scientific literature:

1. Adverse events and complications are common.
2. Many of these complications do not occur with traditional prolapse repairs.
3. Many of these complications are life-altering and permanent, unlike those seen with traditional prolapse repairs.
4. Many of these complications require additional surgery which may or may not alleviate the symptoms - unlike traditional prolapse repairs.
5. The study noted above with 27,809 anterior prolapse surgeries with 49,658 person-years of follow-up determined that the use of mesh for anterior prolapse was associated with an increased risk of any repeat surgery, which was driven by surgery for mesh removal.[47]
6. These complications can occur at any time, unlike complications occurring with traditional prolapse repairs.
7. Explant surgery, when indicated, is risky, difficult to perform, and may or may not alleviate symptoms.

I have concluded the following regarding the differences regarding the mesh complications and those associated with traditional surgery:

1. Many of the complications reported occur only with mesh. These include erosion and extrusion, mesh contraction syndrome, organ perforation from mesh, partner injury, severe vaginal pain, granulomas, and need for multiple surgical procedures for removal and attempted relief of pain.
2. Mesh complications, as opposed to complications with traditional repairs, are likely to be more frequent and more severe. Examples include dyspareunia, de novo stress urinary incontinence, chronic pelvic pain,

[47] Funk, 2012.

neuromuscular injury, and emotional sequelae.

3. Most mesh complications are more difficult to treat. This includes fistulae, bleeding, infection, bowel/bladder injuries, dyspareunia, pelvic pain, and recurrent prolapse.
4. The potential for complications lasts indefinitely because the synthetic mesh is permanent.
5. Some risks are still unknown and cannot be known for many years to come.

Similar literature is available for SUI. Synthetic slings are no more effective than traditional Burch procedure or autologous slings and create unique and, sometimes severe complications.[48] For example, in a randomized controlled trial by Amaro, satisfaction rates were 62.5 to 97.5% in AFS group, while in TVT group it was between 36 to 80%. In this study, AFS and TVT yielded similar results, except for operating time which was shorter in TVT[49]. Chapple recommended that when a patient has made the decision to proceed with surgery, alternative surgical options that include non–mesh-based techniques should be offered, such as an autologous fascial sling or bladder neck suspension.[50]

In a recent review article published in Nature, one of the most prestigious journals in the world, Blaivas described the complications associated with synthetic mesh slings. The most common risks in patients with SMUS include urethral obstruction requiring surgery (2.3% of patients with SMUS), vaginal, bladder and/or urethral erosion requiring surgery (1.8%) and refractory chronic pain (4.1%). At least one third of patients

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[48] e.g. Albo ME, Richter HE, Brubaker L, Norton P, Kraus S, et. al.; Burch colposuspension versus fascial sling to reduce urinary stress incontinence; New England Journal of Medicine 2007;356:2143-2155; Amaro, J. L., Yamamoto, H., Kawano, P. R., Barros, G., Gameiro, M. O. O., & Agostinho, A. D. (2009). Clinical and quality-of-life outcomes after autologous fascial sling and tension- free vaginal tape: a prospective randomized trial. Int Braz J Urol, 35:60-67; Birch, C., & Fynes, M. M. (2002). The role of synthetic and biological prostheses in reconstructive pelvic floor surgery. Curr Opin Obstet Gynecol, 14(5), 527-535; Blaivas, J. G., & Chaikin, D. C. (2011). Pubovaginal fascial sling for the treatment of all types of stress urinary incontinence: surgical technique and long-term outcome. Urol Clin North Am, 38(1), 7-15, v. doi: Blaivas, J. G., Purohit, R. S., Weinberger, J. M., Tsui, J. F., Chouhan, J., Sidhu, R., & Saleem, K. (2013). Salvage Surgery after Failed Treatment of Synthetic Mesh Sling Complications. J Urol. doi: 10.1016/j.juro.2013.03.044; Brown, S. L. & Govier, F. E. (2000). Cadaveric versus autologous fascia lata for the pubovaginal sling: surgical outcome and patient satisfaction. The Journal of Urology, 164:1633- 1637; Broussard, A. P., Reddy, T. G., Frilot II, C. F., Kubricht III, W. S., & Gomelsky, A. (2013). Long- term follow-up of porcine dermis pubovaginal slings. Int Urogynecol J, 24:583-587; Brubaker, L., Richter, H.E., Norton, P.A., Albo, M., Zyczynski, H.M., Chai, T.C., Zimmern, P., Kraus, S., Sirls, L., Kusek, J.W., Stoddard, A., Tennstedt, S., Gormley, A. (2012). 5-Year Continence Rates, Satisfaction and Adverse Events of Burch Urethropexy and Fascial Sling Surgery for Urinary Incontinence J Urology, 187: 1324-1330, 10.1016/j.ucl.2010.12.002.

[49] Amaro, J.L., Yamamato, H., Kawano, P.R. Barros, G., Gameiro, M.O.O., & Agostinho, A.D. (2009). Clinical and quality-of-life outcomes after autologous fascial sling and tension-free vaginal tape; a prospective randomized trial. Int. Braz J. Urol, 35:60-67.

[50] Chapple, C. R., Raz, S., Brubaker, L., & Zimmern, P. E. (2013). Mesh Sling in an Era of Uncertainty: Lessons Learned and the Way Forward. Eur Urol. doi: 10.1016/j.eururo.2013.06.045.

developed recurrent SUI, based on the review. Additionally, complications are under-reported. The authors provide and excellent discussion of the mechanisms by which synthetic slings produce complications – all based on peer-reviewed, reliable medical literature.[51]

Both the American College of Obstetrics and Gynecology and the American Urology Association endorse the use of autologous slings and Burch procedure.[52]

Recent literature is finally addressing the long-term consequences of vaginal mesh complications and the outcomes of attempts at surgical treatment - reporting large numbers of patients in academic medical centers like Emory. This reflects the lag time between the appreciation of these devastating complications for those of us in a referral practice and awareness by community physicians. These studies show a significant number of women who fail to respond to treatment despite the best care available and remain in worse condition than they were before having the initial operation.[53] I am not aware of any other surgical procedure that has created a "new disease" such as that we are seeing since the introduction of trans-vaginal mesh. It has even been given a nae in the recent literature, "Meshology."[54]

In my opinion, the risks of polypropylene mesh in vaginal prolapse and SUI repairs outweigh the benefits.

IV. DISCUSSION OF FINDINGS AND OPINIONS REGARDING PLAINTIFF TINA BURRIS

Brief summary of the medical records concerning Tina Burris:

Clinical Chronology

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[51] Blaivas, et al., Safety considerations for synthetic sling surgery, Nat. Rev. Urol. advance online publication 18 August 2015; doi:10.1038/nrurol.2015.183.

[52] ACOG Practice Bulletin Number 155, November 2015; Dmochowski et al. U t least one-third of patients undergoing sling excision surgery develop recurrent SUI. Update of AUA Guideline on the Surgical Management of Female Stress Urinary Incontinence J Urol ol. 183, 1906-1914, May 2010

[53] e.g. Hammett, J., et al. (2014). "Short-term surgical outcomes and characteristics of patients with mesh complications from pelvic organ prolapse and stress urinary incontinence surgery." Int Urogynecol J 25(4): 465-470; Dunn, G. E., et al. (2014). "Changed women: the long-term impact of vaginal mesh complications." Female Pelvic Med Reconstr Surg 20(3): 131-136; Hansen, B. L., et al. (2014). "Long-term follow-up of treatment for synthetic mesh complications." Female Pelvic Med Reconstr Surg 20(3): 126- 130; Abbott, S., et al. (2014). "Evaluation and management of complications from synthetic mesh after pelvic reconstructive surgery: a multicenter study." Am J Obstet Gynecol 210(2): 163 e161-168; Unger, C A., et al. (2014). "Outcomes following treatment for pelvic floor mesh complications.".

[54] Lee et al., Meshology: a fast-growing field involving mesh and/or tape removal procedures and their outcomes, Expert Rev. Med. Devices Early online, 1–16 (2014).

Date of Implant Surgeries: **8/05/08**.

Implanting Surgeon: Dr. Desrene Kerry-Ann Brown, Bluffton Hospital

Implant Information:

- Product 1: Gynecare Prolift
  - PFRA01
  - LOT #: 3135683 042 LCNP150821A

- Product 2: Gynecare TVT Secur
  - TVTS
  - LOT #: 3118404144 LCNP200621A

Revision Surgeries and procedures:

1. **11/15/2011** - Cleveland Clinic specialists – Dr. Walters vaginal excision of Gynecare Prolift and laparotomy by Dr. Goldman for complications including bladder injury, and left ureter injury, and blood loss anemia requiring blood transfusion.
2. **6/30/15** - Dr. Maurice Chung, bilateral pudendal nerve perineuronal injection and block for chronic pelvic pain and pudendal neuralgia.
3. **8/26/2015** - Dr. Walters – Trachelectomy with vaginal vault suspension and Anterior and Posterior repair for "persistent chronic pelvic pain and recurrent prolapse."

Summary of my expert opinions, specifically with regard to Tina Burris:

1. Ms. Burris' mesh related injuries, which include pudendal neuralgia and/or muscle damage causing groin, leg, and vaginal pain; chronic, long term and life altering pelvic pain; dyspareunia; and painful bladder filling syndrome are the direct result of the defects/features/properties of the TVT-S and/or Prolift devices discussed in this report. Alternatively, the TVT-S and Prolift devices were a cause or significant contributing factor in causing those injuries.

2. I have reviewed the implanting surgeon's operative report and find no evidence of deviation from the Instructions for Use.

3. I performed a differential diagnosis and was able to rule out any other conditions as a primary cause of Ms. Burris' injuries.

4. I have reviewed the relevant Instructions for Use. In my opinion, the warnings provided in the IFUs do not provide doctors with the information needed to make treatment choices and obtain informed consent from their patients,

5. To a reasonable degree of medical certainty, Ms. Burris' injuries would not have occurred with alternative surgical intervention such as the Burch procedure, native tissue repair, or colpopexy. In addition, there were biologic materials, including autologous grafts, allografts and xenografts that would have been safer alternatives, and would have alleviated the complications suffered by Ms. Burris.

6. Ms. Burris' injuries and complications are permanent, and she will require life-time medical and non-medical services throughout her life expectancy.

Relevant medical background and treatment:

Tina Burris [redacted] is a mother of four (G 4, P 4), who first presented to Dr. Brown with problems of uterine fibroids. On 2/19/08, Dr. Brown performed laparoscopic supracervical hysterectomy and bilateral ovarian cyst fulguration. In the following months she complained of symptomatic vaginal prolapse (cystocele) and stress urinary incontinence.

On 8/5/2008, Dr. DK Brown performed surgical repairs including - Anterior repair with Prolift, and placement of TVT Secur. The early post-operative course was uneventful. Urinary urge symptoms were troublesome and unresponsive to medication, and Dr. Brown considered possible Interstim therapy.

In 2011, Ms. Burris presented to Dr. Lawrence J Kuk Jr. of Ada, Ohio with new problems of pelvic and vaginal pain with vaginal discharge and bleeding. Symptoms included dyspareunia, some vaginal bleeding, and some back pain. She was referred on for specialist care to the Cleveland Clinic for assessment and management of worsening pelvic pain after vaginal mesh. Symptoms had been present and worsening for about 6 months, after the onset of pain came vaginal discharge, then vaginal bleeding. It should be noted that Ms. Burris did not return to Dr. Brown who had been the implanting surgeon.

On 8/29/2011, Ms. Burris was examined by urogynecologist Dr. Mark D Walters of the Cleveland Clinic, who documented "anterior Prolift mesh palpable with bleeding area of granulation tissue left mid -to anterior vagina 5 cm into vagina; area somewhat tender". Diagnoses included recurrent Cystocele Stage II, also mesh erosion, dyspareunia and pelvic pain, foreign body in vagina. After discussion it was elected to schedule trans-vaginal removal anterior Prolift mesh, cystocele repair and possible colpopexy.

On November 15, 2011 Ms. Burris returned for pre-op cystoscopy with Dr. Walters, no mesh was seen in the bladder or urethra. The plan was to "leave the TVT

Secur in if not eroded but remove it if exposed". A prescription for opioid (oxycodone) pain medication was given to help manage Ms. Burris's pain. The medical record reflects - "Have you had a recent problem with pain? Yes: LOCATION: lower pelvic area with radiation to back PAIN SCALE: 5-6 on a scale of 0-10 PAIN CHARACTER: crampy, stabbing, sharp, shooting DURATION: 6 months FREQUENCY: occurs constantly" "Does the patient have difficulty performing or completing routine daily living activities? Yes, r/t (as a result of the) pain"

On 11/15/2011, Ms. Burris underwent "Complex transvaginal cystorrhaphy, right double-J stent placement, and open left ureteroneocystostomy, and left open ureteral stent placement" also "Complex transvaginal cystotomy and significant left ureteral injury; Vaginal excision of Prolift mesh and cystoscopy". The operative findings revealed more extensive problems than had been recognized at the time of clinical examination or at pre-operative cystoscopy, the mesh was found to be densely adherent to the bladder wall and left ureter resulting in "unavoidable" surgical injuries to both the urinary bladder and the left distal ureter.

Surgery revealed not one, but two anterior vaginal mesh erosions "mesh erosion in the left proximal arm and in the right distal arm" and Prolift mesh densely adherent to the bladder wall and distal left ureter. The operative report documents – "the Prolift mesh was in the bladder wall at this point and that the cystotomy was unavoidable and part of the mesh excision procedure". Further, "a piece of ureter was integrated with the mesh making us believe that the left distal arm was in close apposition to the left ureter." Also stated, "the left ureterotomy was unavoidable because the mesh was intimately attached to the distal left ureter."

In the course of the procedure, Dr. Howard Goldman of Urology was consulted to repair the bladder and the left ureter. Surgery involved dissecting "the entire bladder and looked within the cystotomy noting that the right ureter was patent. He placed a double -J catheter into the right ureter, so that that could be present during the cystotomy repair. The left ureter had a distal (later) hole was partially transected and so the decision was made to perform an open left ureteroneocystostomy through an abdominal incision." The record reflects - "the sling that is present was not eroded into the vagina and was not palpable. As per our agreement with the patient, we left the TVT Secur sling intact and in situ."

Vaginal mesh pieces were sent for pathology. In the operative record Dr. Walters includes – "COMPLICATIONS: A cystotomy with repair and a left ureterotomy and repair both by Dr.. Goldman, but it was felt that these were an unavoidable part of the surgery because the mesh was in the bladder wall and closely adherent to the left ureter."

The postoperative course was complicated by symptomatic anemia and she required a blood transfusion. Ms. Burris was discharged from hospital with an indwelling Foley catheter for bladder drainage.

The pathology report describes "Vaginal mesh" multiple irregular shaped segments of tan-grey fibro membranous soft tissue admixed with blue synthetic mesh material aggregating 5.4 X 3.8 X 1.3 cm. Pathological diagnosis is recorded as "vaginal mesh excision – benign fibro-adipose tissue with chronic inflammation, giant cell reaction and mesh-type foreign material – Pathologist Andres Roma MD

On 12/1/2011, Ms. Burris returned for cystography that demonstrated no evidence of leak and the indwelling catheter was removed.

On 12/27/2011, Dr. Goldman performed a further cystoscopy to remove the retained bilateral ureteral stents.

On 11/03/14, Ms. Burris presented to Dr. Maurice Chung of the Alliance for Women's Health with persisting symptoms described as "new/old with bladder symptoms and problems with mesh." The record states "she had a TVT with mesh and Prolift in 2008 at Bluffton for a bladder prolapse. She was then seen in 2011 to have some mesh removed due to pain, erosion and states it was coming through the vaginal wall. States today the mesh still causes some pain that she has tolerated for the last 3 years, but now she states she can feel the pressure like her bladder is dropping and it has just gradually become worse over the last year. She c/o urinary urgency, dysuria and several accidents of incontinence. Having pain running down the back of her left leg and pain running down both arms, lower back pain. Having severe fatigue."

On examination, features included atrophic vaginal mucosa and Grade 2 cystocele present. Q-tip test was positive at 6:00 only, negative at 2:00, 4:00, 7:00 and 10:00. Pelvic pain and tenderness was recorded – 4, perineal body tender, right obturator-3, right pubococcygeus-4, Left pubococcgeus-4. The clinical assessment included, Urinary Urgency, Incontinence, Urge, Dyspareunia, Pudendal Neuralgia, Atrophic Vaginitis, pelvic Myofascial pain, Incomplete Bladder Emptying and Post-Void Dribbling.

On 11/05/2014, Ms. Burris was seen again with complaints of urge incontinence, urgency and frequency, and Dr.. Chung ordered urodynamic testing to be done. Assessment included Incontinence, Urge, Urinary Frequency and Urinary Urgency

On 11/26/14, further visit with Dr. Maurice Chung – "The patient is here today to follow up from urodynamic testing after being seen as a new/old early this month with complaints of urge incontinence and muscle and nerve pain. Patient states she is still having a lot of the urgency and has had one accident of leaking since having her urodynamics done. Her biggest complaints are the abdominal and back pain from her previous surgeries, states she has severe pain at work with heavy lifting. Her urodynamic testing showed negative results. Exam from 11/3/14 showed 4 Perineal Body tender, R obturator-3, R pubococcygeus-4, L pubococcygeus-4 VALLEIX: Right tender-3, Left tender-4"

Assessment included Incontinence, urge, Pelvic myofascial pain and Atrophic vaginitis
Ms. Burris was offered Valium tablets 5mg

On 12/12/14, Ms. Burris returned for Potassium Sensitivity study. Complaints were recorded as Back pain, dyspareunia, dysuria, incontinence, pelvic pain, SUI, and urgency.
Assessment included Dysuria, Urinary Urgency and Chronic Pelvic Pain

On 1/05/15, Ms. Burris was seen again by Dr. Chung who recorded chief complaints of:

- Urge Incontinence
- Myofascial pain
- Urgency
- Pudendal Neuralgia
- Atrophic Vaginitis
- Post-Void Dribbling
- Incomplete Bladder Emptying

History of Present Illness includes – "She presents to the office today to follow up a mild positive on a PST. The patient had a PST done 12/12/14. Results were mild positive with Solution B. On last exam, pt had a grade 2 cystocele. Patient also reported pain on the RO rating a 3, the LO rating a 4, the RPC rating a 3, and the LPC rating a4. Patient states she often feels pain that feels like a rubber band is being flicked at her."

Further medication was prescribed - Elmiron oral capsule 100 mg tid and Dr. Chung provided a work excuse for a one month absence from work.

On 1/06/15, Ms. Burris had the first of a series of Rescue Rinse urinary bladder washes for painful bladder syndrome. History was recorded – "Urgency 8/10; Frequency 6-7 times; Pain 5/10; Nocturia 0. Relief with RR first time."

On 1/12/15, Rescue Rinse #2 "Urgency 8/10; Pain 5/10; Nocturia 0. Relief with RR first time, watching what she eats."

On 1/14/15, Rescue Rinse #3 "Urgency 7/10; Frequency 6x; Pain 4/10; Nocturia 0."

On 1/16/15, Rescue Rinse #4 - Urgency 8/10; Frequency 6-7; Pain 10/10; Nocturia 0. Relief: "I was getting some, but now it's worse."

1/19/15 to 1/29/19 Rescue Rinse #5, #6, #7, #8 – Urgency 8/10; Frequency 6; Pain 8/10; Nocturia 0. Relief: "Not having very much relief after rinses and is having bladder

spasms for two days following each rinse." My last rinse, "I only had relief for an hour or so."

On 2/2/15, reviewed by Dr. Maurice Chung Follow-up after a course of 8 Rescue rinses. "The patient is following up today after her 8th rinse patient states she did not have many complaints of urinary problems just pelvic pain that she rates a 2/10 today but usually gets up to an 8/10 on a daily basis, states after getting a rinse she would have relief for maybe an hour on occasion she would be back in pain when getting out to the parking lot. The patient had a PST (potassium sensitivity test) done 12/12/14. Results were mild positive with Solution B. On last exam, patient had a grade 2 cystocele.

Recommendations included MRI of the spine with contrast to rule out possible herniated disc, Physical therapy and medication for pain control - Gabapentin

On 2/19/15, MRI of Lumbar Spine, Lima Memorial Health Systems – the findings were unremarkable.

On 3/11/15 Further follow-up with Dr. Chung - chief complaint was back pain and abdominal pain. "The patient states she never did physical therapy. She is taking the Neurontin (Gabapentin) 300mg one in the morning and two at HS. She doesn't feel like it's helping much and she now has nocturia that she never had before. She is also doubling her Elavil at hs. (Before bed)"

The clinical assessment included Pelvic myofascial pain improving, back pain worsening and herniated lumbar intervertebral disc. Further medication was prescribed - adding Anaflex oral tablet 4mg in addition to:

- Diazepam oral tablet 10mg
- Elmiron oral capsule 100mg
- Gabapentin oral capsule 300mg
- Strongly recommend physical therapy

On 3/26/15, Susan Hubbell, MD of Physical Medicine Associates of NW Ohio evaluated Ms. Burris for Physical Therapy Prescription:

- Pelvic floor exercises for incontinence and pelvic pain and spine ergonomics.
- 2 times a week for 8 weeks

Chronic Problems listed included DDD (Degenerative disc disease) lumbar, OA (Osteoarthritis) lumbar/ LS (lumbosacral) spine, Pelvic peritoneal adhesions and Lumbago/ Low back pain

Clinical Evaluation includes – "Patient is a 49-year-old female who complains of pain in her back rated at a 3/10 within the last 24 hours, and that her average pain is 4/10. Her pain is described as stabbing, sharp, squeezing, throbbing, cramping, and shooting. It is aggravated during movement, sitting and standing, but gets relief when she lays down. Her pain interferes with her mood, walking ability, normal work, sleep, cleaning, and enjoyment of life."

"She states that she takes Gabapentin x3 per day and that helps, as well as Amitriptyline at bed time to sleep. She worked for 8 years at Ohio Northern as janitor until the pain required her to stop. She does not think she is any better since she has stopped work."

"She reports numbness of her feet. She gets pain radiating from her buttock down the back of her leg and had been told she has "sciatica". Sometimes both of her legs are involved. When she walks, she gets tingling in her feet. She has no incontinence of bowel and is not constipated."

Past Medical History includes – "Positive for chronic back pain and interstitial cystitis with problems with her bladder. She is not diabetic and has no history of hypertension, heart disease, kidney or liver disease. Dr.. Chung's records describe bladder surgery, endometrial resection, supracervical hysterectomy, and vaginal anterior repair with mesh. She is treated for depression, kidney stones, pudendal neuralgia, and pelvic myofascial pain."

Clinical Impression includes:

1. Osteoarthritis of the lumbar spine.
2. Degenerative disc disease of the lumbar spine.
3. Low back and leg pain.
4. Interstitial cystitis.
5. Pelvic myofascial pain.

On 4/20/15, Ms. Burris returned to Dr. Maurice Chung, for a one month follow-up "Patient states she has her days of worse pain--depending on what patient does during the day. Pt has started the physical therapy, states it is going well. Pt goes every Tuesday and Friday. Patient is wondering if she has a mild case of spinal stenosis. Pt was told it was mild but states it hurts too bad to be mild."

On physical examination, "mild tenderness to palpation present in the uterus" was recorded. Clinical assessment included:

1. Left pelvic Myofascial pain worsening.
2. Back pain worsening.

3. Herniated lumbar intervertebral disc.
4. Left lower abdominal pain worsening.
5. Depression.

On 4/21/15, Dr. Chung performed left abdomen myofascial trigger point injections.

At follow up on 4/29/15, Ms. Burris reported "about 75% improvement with her pelvic pain until yesterday. The pain started back yesterday #2-3/10, today is also #2/10 "but I can live with that". Patient has no desire to have any more trigger point injections. 70% better."

Clinical assessment:

1. Abdominal pain improving.
2. Pelvic myofascial pain improving

On 5/22/15, Ms. Burris returned to Susan Hubbell, MD for office visit "Follow-up for low back pain and pelvic pain. She did go to physical therapy at Lima Memorial for 11 sessions. Unfortunately, the only physical therapist that dose pelvic floor therapy does not take her insurance. She said that the physical therapy was "helpful." "Dr.. Chung did a trigger point injection, and thinks that has helped." Clinical impression was "Some improvement after physical therapy to her low back pain."

Plan:

1. Discussion that pain is generating from multiple areas and that any one treatment will not take care of all the pain. Physical therapy is to work on her low back and hip pain and the Dr. Chung will be addressing the pelvic area.
2. Provided pelvic floor exercise handout to complete at home.
3. Encouraged physical therapy; however, will stop physical therapy due to hardship of traveling to Lima for the program.

On 6/30/15, Maurice Chung, MD of Lima Memorial Health System performed bilateral pudendal nerve perineuronal injection and block for chronic pelvic pain and pudendal neuralgia. Procedure included bilateral pudendal nerve perineuronal injection and block. Injection was placed to the left ischial spine perineuronal region. After injection on the left side, the procedure was then directed to the right side.

On 8/26/2015, Dr. Walters performed further vaginal surgery – Trachelectomy (removal of the cervix) with vaginal vault suspension and Anterior and Posterior repair for "persistent chronic pelvic pain and recurrent prolapse". (Grade 3) The TVT Secur was not removed nor revised at that time.

1. Findings Normal appearing cervix.
2. Stage 3 cervicovaginal prolapse well supported at the conclusion of the procedure.
3. Adequate vaginal length and caliber at the conclusion of the procedure.
4. No trauma suture or foreign body in the bladder, clear ureteral efflux of fluorescein in right UO, left reimplanted UO with probable efflux.
5. Scar from prior midline cystotomy, visualized well heated.

Pre-op/Pre-procedure Diagnosis: cervicovaginal prolapse.

Operative Indications:

Presented with recurrent stage 3 cervicovaginal prolapse. She initially underwent supracervical hysterectomy with subsequent anterior Prolift and TVT secure sling. She then experienced anterior vaginal wall mesh erosion with pain and vaginal discharge. She had a vaginal excision of mesh at which time she had a cystotomy and urethrotomy (ureterotomy), which were repaired intraoperatively both vaginally and abdominal left ureteral reimplantation. It appeared that her Prolift mesh was imbedded in the wall of the bladder. After this procedure her urinary tract function returned to normal, she had multiple normal renal ultrasounds preoperatively but she has persistent chronic pelvic pain and recurrent cervicovaginal prolapse.

Operative Procedure:

"First, the vaginal trachelectomy was performed. The uterosacral vaginal vault suspension was then performed. The anterior vaginal wall was evaluated we proceeded with anterior repair. We took extra care with dissection due to scarring from prior repair and in order to avoid cystotomy. Next, the uterosacral vaginal vault stitches were anchored. We performed careful survey for 30 minutes to ensure patency and look for third ureteral orifice. It was not able to be identified despite through evaluation. There was very little concern for any ureteral obstruction given reassuring cysto findings and location of the suspension from the reimplanted ureter."

The final note in the available medical records is on 04/20/17, Rheumatologist, Obie L Ramsay M.D. was consulted for ongoing problems of pain with symptoms of chronic fatigue. Radiographic studies were done to exclude evidence of generalized arthritis or tissue swelling that might support a rheumatic or arthritic cause. The studies revealed no evidence of arthritis or soft tissue abnormality.

Tina Burris has experienced mesh-related complications including recurrent vaginal mesh exposures, vaginal pain, chronic pelvic pain, dyspareunia, pudendal neuralgia, urinary urgency, urinary incontinence and bladder dysfunction. These are caused primarily by the Prolift anterior device with the TVT-Secur, more likely than not, a

significant contributing factor. These injuries are the direct result of the defects inherent in these devices, including source of chronic inflammation, foreign body reaction, shrinkage, deformation, scarring and fibrosis, hardening, nerve damage, and degradation of the polypropylene mesh. These injuries were foreseeable based on experience with hernia mesh and the use of mesh in other pelvic applications.

Ms. Tina Burris's care and treatment met the standard of care. Specifically, the implant operative note does not reveal any errors in surgical technique. Ethicon did not provide guidance on the management of complications for doctors using their products. There were safer alternatives that would have avoided the injuries experienced by Ms. Burris, including native tissue repairs, paravaginal repairs and colpopexy. In addition, there were devices biologic materials, including autologous grafts, allografts and xenografts that would have been safer alternatives, and would have alleviated the complications sufferance by Ms. Burris.

I performed a differential diagnosis to reach these conclusions. Exposure of mesh and erosion of mesh are unique complications of mesh. Ms. Burris did not have any significant pelvic pain issues nor dyspareunia prior to implantation of the vaginal mesh products. Ms. Burris is menopausal and, like all women who are menopausal, has some degree of vaginal atrophy. Likewise, this is not the cause of her vaginal symptoms and exam findings. Vaginal atrophy does not produce focal pain or findings and is treatable with local estrogen. Past history of kidney stones did not help to explain the clinical course. Endometrial resection in 2003 and supracervical hysterectomy in 2008 did not contribute to the ongoing clinical symptoms.

Dr. Brown, the implanting surgeon was aware of the initial symptoms of urinary urgency and frequency, but did not recognize the vaginal mesh erosion that came later. Dr. Kuk first diagnosed the mesh complication, but had not been trained to manage the complications of Prolift, instead Ms. Burris had to be referred on to seek help from a mesh retrieval specialist at the Cleveland Clinic. Referral was clearly needed in this case because the revision surgeries proved to be complex and complicated by unavoidable surgical injuries not only to the bladder, but also to one ureter.

Clinical evaluation had underestimated the extent of the problem. The operative findings revealed not only one, but two anterior vaginal mesh erosions "mesh erosion in the left proximal arm and in the right distal arm" and Prolift mesh densely adherent to the bladder wall and distal left ureter. The operative report documents – "the Prolift mesh was in the bladder wall at this point and that the cystotomy was unavoidable and part of the mesh excision procedure". Further, "a piece of ureter was integrated with the mesh making us believe that the left distal arm was in close apposition to the left ureter." Also stated, "the left ureterotomy was unavoidable because the mesh was intimately attached to the distal left ureter." The urogynecology specialist Dr. Walters had to call on Dr. Goldman to come to the operating room to assist in the surgical repairs, and excessive blood loss resulted in the need for post-operative blood transfusion.

Dr. Walters performed surgical revision with excision of the eroded Prolift, more than 3 years after the initial mesh placement. This case reflects a very common feature of mesh complications, that problems typically occur years after implantation; the medical literature is burgeoning with reports of single center series with only short term follow up and these studies by definition are blind to late and long-term patterns of complication. This may help to explain why the private practitioners of gynecology and urology have been so much slower than academic pelvic surgeons to recognize the inherent dangers of vaginal mesh design.

I reviewed the IFUs for the Prolift and TVT-S devices. In no way, does the IFU describe the injuries experienced by Tina Burris. The IFUs do not provide information regarding the frequency, severity, lack of responsiveness to treatment, and permanence of complications associated with the product. They provide no guidance to doctors on ways to manage these complications. The IFUs misrepresent the material properties of polypropylene by describing "a minimum to slight inflammatory response, which is transient", a "deposition of a thin fibrous layer of tissue", and "soft and pliable". The IFUs also state that the mesh is not "subject to degradation or weakening by the action of tissue enzymes." The peer-reviewed scientific and medical literature clearly contradicts these statements. The IFUs incorrectly state that a "transitory local irritation at the wound site and a transitory foreign body may occur".

The IFUs also misrepresent the life-changing and unique complications associated with transvaginally placed mesh devices by stating "potential adverse reactions are those typically associated with surgically implantable materials". This is inconsistent with the medical literature and my clinical experience. The IFUs do not address the potential for ongoing adverse events. They do not address the recalcitrant and recurrent nature of many vaginal mesh exposures and erosions. The IFUs do not address the risk of permanent vaginal scarring and distortion, chronic pain, sexual impairment, and dyspareunia. The IFUs do not inform physicians of the difficulty and risks involved in removing these devices, the need for multiple surgeries, or the failure of surgery to correct the problems in many cases.

Ms. Burris's prognosis is guarded due to the chronicity of her symptoms and the presence of retained Prolift arms. In addition to the remaining mesh in the anterior compartment, the TVT-S is still in place, and it is likely that she will require additional medical, and even further surgical treatment to address her ongoing chronic pelvic pain and other symptoms.

In my opinion, the TVT-S and Prolift devices used in Ms. Tina Burris were unreasonably dangerous because the risks far outweighed the benefits, Ethicon did not warn doctors and patients of the serious risks, and Ethicon made inaccurate and misleading representations as to safety of the devices. These devices were unreasonably dangerous because Ethicon did not provide Ms. Tina Burris or her doctors with accurate

and complete information and warnings. Finally, claims made by Ethicon regarding the products' performance that were known to be misleading or untrue make the products unreasonably dangerous.

I reserve the right to supplement my opinions regarding her injuries and reasonable necessity of future care as her prognosis develops.

V. EXHIBITS

My current curriculum vitae is attached here to as Exhibit "A."

All exhibits that will be used to support my findings and opinions or documents/data that I have reviewed in connection with this report and/or referenced herein are listed in Exhibit "B," as well as:

Medical records of Tina Burris

Ethicon's Instructions for Use

Prior Expert Reports of Dr. Niall Galloway, *IN RE: ETHICON INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION, MDL No. 2327*

Expert reports of Dr. Jerry Blavis, *IN RE: ETHICON INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION, MDL No. 2327*

VI. RECENT TESTIMONY

To the best of my knowledge, in the previous four years, I have testified, by deposition or in trial, in the cases identified on the attached Exhibit "C".

VII. COMPENSATION

The compensation which I expect to be paid for this case is as follows:

Record Review or Review of Deposition Testimony $600/hour.

Final Report (required in this case) $6,000.

Future time to be spent in Deposition or in Court appearance, if needed $1,000/hour.

I declare under penalty of perjury that the foregoing is true and correct.

Niall T M Galloway, MB, FRCS

August 18th, 2019